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ELECTRONIC

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/588,489	08/04/2006	Eric Perouse	2006_1244A	6680	
513 WENDEROTE	7590 04/28/201 I. LIND & PONACK, 1	EXAMINER			
1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503			TANNER, JOCELIN C		
			ART UNIT	PAPER NUMBER	
	0 20000 1000		3731		
			NOTIFICATION DATE	DELIVERY MODE	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com eoa@wenderoth.com

Application No. Applicant(s) 10/588,489 PEROUSE, ERIC Office Action Summary Examiner Art Unit JOCELIN C. TANNER 3731 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

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WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, "HEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Isoms of time may be available under the provisions of 3 CFR 1-136(a), in no event, however, may a reply be timely fixed prior of for reply is specified above, the maximum statutory period will apply and will expire SK (6) MONTHS from the mailing date of this communication, to reply within the set or extended period for reply will by statute, cause the application to become ABANDONED (3S U.S.C. § 133), oply received by the Office later than three months after the mailing date of this communication, even if timely filled, may reduce any dy drate term enallyments. Set 3 CFR 1-704(b).					
Status						
1)🖂	Responsive to communication(s) filed on 1/15/2010.					
2a)⊠	This action is FINAL. 2b) This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposit	on of Claims					
4)⊠	Claim(s) <u>25-44</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)	Claim(s) is/are allowed.					
6)⊠	☐ Claim(s) 25-44 is/are rejected.					
7)	Claim(s) is/are objected to.					
8)□	Claim(s) are subject to restriction and/or election requirement.					
Applicat	on Papers					
9)	The specification is objected to by the Examiner.					
	The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11)	The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority (ınder 35 U.S.C. § 119					
12)	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a)	☐ All b) ☐ Some * c) ☐ None of:					
	 Certified copies of the priority documents have been received. 					
	2. Certified copies of the priority documents have been received in Application No					
	3. Copies of the certified copies of the priority documents have been received in this National Stage					
	application from the International Bureau (PCT Rule 17.2(a)).					
* 5	See the attached detailed Office action for a list of the certified copies not received.					
Attachmen						
1) X Notic	e of References Cited (PTO-892) 4) Interview Summary (PTO-413)					

U.S	Patent and	Trade	mark	Offic
PT	OL-326 (Rev.	08-	06)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (FTO/SB/08) Paper No(s)/Mail Date _____

Paper No(s)/Mail Date. ___

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

This Office Action is in response to the Amendment filed 15 January 2010. Claims 25-44 are currently pending. The Examiner acknowledges the amendments to claims 25, 30, 36 and 41.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be neadtived by the manner in which the invention was made.
- Claims 25-32, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713).
- 3. Regarding claim 25, Berg et al. discloses a deformable lattice (30) including a silicone covering coating crossed nitinol wire arranged to define meshes, connectors (34) including two external hooks having hook portions (52, Fig. 6a) that are capable of defining a clamp for anchoring the prosthesis to tissue, at least two hooks formed of flexible nitinol material and mounted to the lattice at opposite sides of one of the meshes (Fig. 3), the hooks being capable of moving from a spaced apart position such that the clamp is open and a close-together position wherein the clamp is closed (Figs. 10a, 10b). However, Berg et al. fails to expressly disclose the lattice having a retracted state wherein the lattice has a small diameter and expanded state wherein the lattice has a larger diameter such that the meshes are capable of having a first shape when

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the lattice is contracted such that the hooks are spread apart and a second shape when the lattice is expanded such that the at least two hooks of the clamp are in a close-together position.

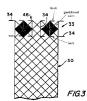
Goldsteen et al. teaches tubular member formed of a nitinol frame (432) and a coating of a highly elastic material, i.e. silicone, the tubular member including a radially compressed configuration and a radially expanded configuration, wherein the meshes are compressed and expanded within the lattice thus being capable of opening and closing the clamps of Berg et al. (column 3, lines 8-35, column 12, lines 26-47, Fig. 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Berg et al. with means to expand and compress, as taught by Goldsteen et al., to allow the lattice to stay open and be distensible so that it may pulsate like natural circulatory system tubing in response to pressure waves in the blood flow (column 12, lines 40-45).

Berg et al. ('713) teaches a graft connector having a medial portion (16) therebetween axially extending fingers (14) wherein the free ends of the fingers overlap when the graft is installed within a patient (column 9, lines 1-9, Fig. 17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Berg et al. and Goldsteen et al. with overlapping hooks, as taught by Berg et al. ('713), to help increase the contact area between the hooks and the tissue between them and the compression of the tissue between the fingers (column 9, lines 5-8).

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- 4. Regarding claim 26, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses at least two hooks having a connection end that is connected to the lattice and capable of moving relative to each other during deformation of the lattice from a retracted to an expanded configuration.
- Regarding claim 27, Berg et al. ('048) discloses meshes of a lattice having a shape of a deformable quadrilateral wherein the at least two hooks are connected to the lattice at a respective corner of the meshes. Please see figure above.
- Regarding claim 28, Berg et al. ('048) discloses the connection end of the hooks may be attached to the lattice by welding (column 5, lines 23-25).
- Regarding claim 29, Berg et al. ('048) discloses at least two hooks having a strand twisted connection end to the lattice (column 5. lines 1-20).
- 8. Regarding claim 30, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses crook portions of at least two hooks (Fig. 6a, Berg et al. ('048)) and at least two hooks that are shaped and arranged to at least partly overlap when the lattice is in an expanded state so as to form a clamp (Fig. 17, Berg et al. ('713)).

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- 9. Regarding claim 31, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses that each hook may be in the form of a substantially rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open and the lattice is in an expanded state (Figs. 3, 7b, Berg et al. ('048), Fig. 17, Berg et al. '713).
- Regarding claim 32, Goldsteen et al. discloses a lattice that is elastically deformable towards an expanded position (column 12, lines 40-45).
- 11. Regarding claim 34, Berg et al. ('048) discloses a lattice having a tubular shape and at least two hooks (3310) that are offset circumferentially with respect to each other around the tubular prosthesis (3300) (Fig. 33).
- 12. Regarding claim **35**, Berg et al. discloses two hooks that are offset circumferentially by a first circumferential spacing with respect to each other around the tubular shaped lattice when the hooks are in a spaced-apart position (Fig. 3), the at least two hooks are offset circumferentially by a second circumferential spacing when the two hooks are in a close-together position that is smaller than the first circumferential spacing (Figs. 17, Berg et al. ('713)).
- 13. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713), as applied to claim 25 above, and further in view of Schwartz et al. (US Patent No. 5,443,496).

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14. Regarding claim 33, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses all of the limitations previously discussed except for a stretchable liquid-proof film.

Schwartz et al. teaches a lattice formed of wire having a polyurethane film disposed thereon wherein the film is capable of stretching to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the lattice of the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) with the stretchable polyurethane film, as taught by Schwartz et al., to provide a biocompatible polymeric surface to contact and support a body lumen and to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

- 15. Claims 36-42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713) in view of Perez et al. (US Patent No. 6,984,244).
- 16. Regarding claim 36, Berg et al. discloses a deformable lattice (30) including a silicone covering coating crossed nitinol wire arranged to define meshes, connectors (34) including two external hooks having hook portions (52, Fig. 6a) that are capable of defining a clamp for anchoring the prosthesis to tissue, at least two hooks formed of flexible nitinol material and mounted to the lattice at opposite sides of one of the meshes (Fig. 3), the hooks being capable of moving from a spaced apart position such

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that the clamp is open and a close-together position wherein the clamp is closed (Figs. 10a, 10b). However, Berg et al. fails to expressly disclose the lattice having a retracted state wherein the lattice has a small diameter and expanded state wherein the lattice has a larger diameter such that the meshes are capable of having a first shape when the lattice is contracted such that the hooks are spread apart and a second shape when the lattice is expanded such that the at least two hooks of the clamp are in a close-together position.

Goldsteen et al. teaches tubular member formed of a nitinol frame (432) and a coating of a highly elastic material, i.e. silicone, the tubular member including a radially compressed configuration and a radially expanded configuration, wherein the meshes are compressed and expanded within the lattice thus being capable of opening and closing the clamps of Berg et al. (column 3, lines 8-35, column 12, lines 26-47, Fig. 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Berg et al. with means to expand and compress, as taught by Goldsteen et al., to allow the lattice to stay open and be distensible so that it may pulsate like natural circulatory system tubing in response to pressure waves in the blood flow (column 12, lines 40-45).

Berg et al. ('713) teaches a graft connector having a medial portion (16) therebetween axially extending fingers (14) wherein the free ends of the fingers overlap when the graft is installed within a patient (column 9, lines 1-9, Fig. 17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Berg et

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al. and Goldsteen et al. with overlapping hooks, as taught by Berg et al. ('713), to help increase the contact area between the hooks and the tissue between them and the compression of the tissue between the fingers (column 9, lines 5-8).

Perez et al. teach a medical repair device delivery system wherein a repair device or "lattice" (390) is encompassed by a capsule or "holding means" (FIG. 12, element #333) which restrains the repair device and prevents its deployment (column 12, lines 63-64). The lattice is secured by its distal end to an inner catheter or "delivery tube" (FIG. 12, element #320) which restricts the repair device from deployment and delivers the device to the treatment site. The hooks (FIG. 2, element #96) are pressed into the grooves or "channels" (FIG. 14, element #376) arranged within the stop ring or "confinement duct" (FIG. 12, element #370) of a lattice delivery tube that is attached to the distal end of the inner catheter. The holding means prevents the hooks from contacting the sheath assembly (column 12, lines 65-68, FIG. 13, element #340). The hooks are free to embed in the vasculature once the capsule and sheath assembly are retracted (column 13, lines 12-13, column 14, lines 15-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retaining device for holding the lattice of the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) in a retracted state, as taught by Perez et al., for the predictable result of preventing the hooks from piercing the tissue prior to installation.

 Regarding claim 37, Perez et al. discloses longitudinal grooves wherein hooks are disposed therein (column 13, lines 40-46).

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- 18. Regarding claim 38, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses at least two hooks having a connection end that is connected to the lattice and capable of moving relative to each other during deformation of the lattice from a retracted to an expanded configuration.
- 19. Regarding claim 39, Berg et al. ('048) discloses meshes of a lattice having a shape of a deformable quadrilateral wherein the at least two hooks are connected to the lattice at a respective corner of the meshes. Please see figure above.
- Regarding claim 40, Berg et al. ('048) discloses the connection end of the hooks may be attached to the lattice by welding (column 5, lines 23-25).
- 21. Regarding claim 41, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses crook portions of at least two hooks (Fig. 6a, Berg et al. ('048)) and at least two hooks that are shaped and arranged to at least partly overlap when the lattice is in an expanded state so as to form a clamp (Fig. 17, Berg et al. ('713)).
- 22. Regarding claim 42, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses that each hook may be in the form of a substantially rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open and the lattice is in an expanded state (Figs. 3, 7b, Berg et al. ('048). Fig. 17. Berg et al. ('713).
- 23. Regarding claim 44, Berg et al. ('048) discloses a lattice having a tubular shape and at least two hooks (3310) that are offset circumferentially with respect to each other around the tubular prosthesis (3300) (Fig. 33).

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24. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713) in view of Perez et al. (US Patent No. 6,984,244), as applied to claim 36 above, and further in view of Schwartz et al. (US Patent No. 5,443,496).

25. Regarding claim 43, the combination of the combination of Berg et al. ('048), Goldsteen et al., Berg et al. ('713) and Perez et al. discloses all of the limitations previously discussed except for a stretchable liquid-proof film.

Schwartz et al. teaches a lattice formed of wire having a polyurethane film disposed thereon wherein the film is capable of stretching to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the lattice of the combination of Berg et al. ('048), Goldsteen et al., Berg et al. ('713) and Perez et al. with the stretchable polyurethane film, as taught by Schwartz et al., to provide a biocompatible polymeric surface to contact and support a body lumen and to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

Response to Arguments

26. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Jocelin C. Tanner/ 4/20/2010 Examiner, Art Unit 3731

/Anhtuan T. Nguyen/ Supervisory Patent Examiner, Art Unit 3731 4/25/10